

EFFICACY REVIEW

PRODUCT: Advantage Plus 10 for Dogs, Advantage Plus 20 for Dogs, Advantage Plus 55 for Dogs, Advantage Plus 100 for Dogs

FILE SYMBOL: 11556-REI, 11556-REL, 11556-RET, 11556-RGN

DATE: August 6, 2007

DP BARCODE: D342416, D342417, D342418, D342419

DECISION NUMBER: 215323, 215314, 215321, 215493

GLP: No

CHEMICAL: Imidacloprid (9.1%)

CHEMICAL NUMBER: 129099

PURPOSE: Review data to support the addition of dog lice (*Trichodectes canis*)

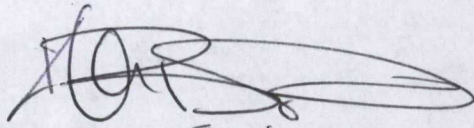
MRID: 47190401. Doyle, J., Egan, T. (2006) A Controlled Randomised Study to Evaluate the Efficacy of Advantage Against a Natural Infestation of Dog Lice (*Trichodectes canis*) Following a Single Topical Administration to Adult Mixed Breed Dogs: Final Study Report. Project Number: 144/914, 75950. Unpublished study prepared by Charles River Laboratories BioLabs Europe. 130p.

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8-6-07

BACKGROUND:

Advantage Plus 10, Advantage 20, Advantage 55 and Advantage 100 are ready-to-use spot on treatments for dogs intended for the month long control of fleas and lice. The proposed labels contained the following label claims concerning lice:

1. Once-A-Month Topical Treatment for Fleas and Lice
2. Kills [(biting) (chewing)] lice
3. Kills [(biting) (chewing)] lice, which may serve as intermediate hosts for tapeworms (*Dipylidium caninum*)
4. Kills [(biting) (chewing)] lice and prevents further infestations

DATA REVIEW:

The following data review is comprised of explanations of materials and methods, and a summation of experimental results containing tables with reformatted data.

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The experimental design consisted of separating 20 dogs into two groups of ten containing both males and females. All dogs included in the study were naturally infested with dog lice (*Trichodectes canis*) and had a minimum of 10 infesting lice. Group 1 acted as a control, while dogs within the second group were treated (via spot treatment) with 0.1 mL/kg bodyweight of Advantage on day 0. Observations on efficacy were taken on days 1, 2, 7, 14, 21, 28 and 36.

Results:

Table 1. Lice Counts

Group	Animal	Total Number of Lice								
		Day - 7	Day - 3	Day 1	Day 2	Day 7	Day 14	Day 21	Day 28	Day 36
Control	1	-	52	-	86	92	52	52	95	68
	2	-	-	77		66	63	72	-	90
	3	21	29	54	9	3	0	0	0	0
	4	20	80	13	15	1	0	0	0	0
	5	85	44	61	88	64	49	81	85	44
	6	79	36	53	-	80	76	57	83	89
	7	-	70	61	88	66	59	97	99	81
	8	31	37	32	46	37	16	13	25	42
	9	-	-	-	-	99	94	91	75	
	10	-	72	-	-	95	65	65	69	49
Treatment	1	36	29	3	0	0	0	0	0	0
	2	-	67	1	0	0	0	0	0	0
	3	-	74	4	5	0	2	0	0	0
	4	-	96	16	10	0	0	0	0	0
	5	-	91	20	6	0	0	0	0	0
	6	-	-	68	13	0	0	0	0	0
	7	59	47	0	0	0	0	0	0	0
	8	-	42	22	0	0	0	0	0	0
	9	73	41	1	0	0	0	0	0	0
	10	41	35	4	0	0	0	0	0	0